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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/785,215	02/20/2001	Martin Roland Jensen	3631-0107P	7660

2292 7590 10/12/2004

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EXAMINER	
NICHOLS, CHRISTOPHER J	
ART UNIT	**PAPER NUMBER**
1647	

DATE MAILED: 10/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/785,215	JENSEN ET AL.	
	Examiner	Art Unit	
	Christopher J Nichols, Ph.D.	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 July 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,4,7-10,15-19,25-29,33,59,60 and 62-76* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,4,7-10,15-19,25-29,33,59,60 and 62-76* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *See Continuation Sheet* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *20 February 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *5.14.04 8.3.04*. 8/2/04
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims subject to restriction and/or election requirement are 1,3,4,7-10,15-19,25-29,33,59,60 and 62-76.

DETAILED ACTION

Status of Application, Amendments, and/or Claims

1. The Response and Amendment filed 30 July 2004 has been received and entered in full.

2. The Preliminary Amendment filed 20 February 2001 has been received and entered in full.

3. The Preliminary Amendment filed 8 August 2001 has been received and entered in full.

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Withdrawn Objections And/Or Rejections

5. The Objection to the Oath as set forth at ¶9 pp. 3 in the previous Office Action (30 January 2004) is hereby *withdrawn* in view of Applicant's submission of a substitute Oath on 17 May 2004.

6. The Objection the Specification as set forth at ¶10 pp. 3 in the previous Office Action (30 January 2004) is hereby *withdrawn* in view of Applicant's amendments (30 July 2004).

7. The Objection to claims **1, 15,** and **60** as set forth at ¶11-13 pp. 4 in the previous Office Action (30 January 2004) is hereby *withdrawn* in view of Applicant's amendments (30 July 2004).

8. The Rejection of claims **1, 3, 4, 7-10, 12-19, 25-29, 33,** and **59-68** under 35 U.S.C. §112 ¶1 as set forth at ¶16-21 pp. 5-8 in the previous Office Action (30 January 2004) is hereby *withdrawn* in view of Applicant's amendments (30 July 2004).

9. The Rejection of claims **3, 4, 12,** and **61** under 35 U.S.C. §112 ¶1 as set forth at ¶22-27 pp. 8-10 in the previous Office Action (30 January 2004) is hereby *withdrawn* in view of Applicant's amendments (30 July 2004).

10. The Rejection of claims **3** and **12** under 35 U.S.C. §112 ¶2 is as set forth at ¶28-30 pp. 10-11 in the previous Office Action (30 January 2004) is *withdrawn* in view of Applicant's amendments (30 July 2004).

Maintained Objections And/Or Rejections

Non-Statutory Obvious-Type Double Patenting

11. Claims **1, 3, 4, 7-10, 15-19, 25-29, 33, 59, 60,** and **62-76** are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-22 of copending Application No. 10/204,362.

Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to a method involving administration of a compound comprising autologous Aβ or autologous APP wherein is introduced at least on isolated foreign T-helper epitope and wherein said compound induces production of antibodies against autologous Aβ or autologous APP. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

12. Claims **1, 3, 4, 7-10, 15-19, 25-29, 33, 59, 60,** and **62-76** are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-21 of copending Application No. 10/223,809. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to a method involving administration of a compound comprising autologous Aβ or autologous APP wherein is introduced at least on isolated foreign T-helper epitope and wherein said compound induces production of antibodies against autologous Aβ or autologous APP. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

13. Claims **1, 3, 4, 7, 9, 15, 16, 17, 18, 19, 25, 26, 27, 28, 29, 33, 59, 60, 62, 64, 65, 66, 67, 68, 69, 70, 71, 72, 73, 74, 75,** and **76** are rejected under 35 U.S.C. 102(e) as being anticipated by US 6,787,637 (7 September 2004) Schenk.

14. US '637 teaches a method of treating a disease associated with amyloid deposits of Aβ in the brain of a patient including but not limited to Alzheimer's disease and/or Down's syndrome comprising administering an immunogenic Aβ fragment conjugated to a T helper cell and/or B-cell epitope thus meeting the limitations of claims 1, 70, 71, 73, 74, and 76 (Col. 3 lines 15-65; Col. 11 lines 55-65).

15. The teachings of US '637 include all natural human amino acid sequences as well as analogs such as but not limited to allelic, species, and induced variants of Aβ and APP including APP770. Also the sequence listings of US '637 fully encompass the residues 672-714 and 700-714 of the amino acid sequence of instant SEQ ID NO: 2 (see Sequence Listing; Col. 11 lines 20-35).

16. The teachings of US '637 include but are not limited to helper T cells such as tetanus toxoid, diptheria, influenza Hemagluttinin HA, malaria CS (*P. falciparum* is the causative agent of malaria thus the two epitopes are the same), and MHC II epitopes thus meeting the limitations of claims 10, 59, 60, and 69 (Col. 20 lines 20-60).

17. US '637 teaches a "first moiety" B-cell antigen, a "second moiety" IL-1, IL-2, IL-12, M-CSF, and a "third moiety" 3 De-O aceylated monophosphoryl lipid A, copolymers, lipids, cellulose (a carbohydrate), agarose, polyethylene glycol, thus meeting the limitations of claim 3, 62, 64, 72, and 75 (Col. 28 lines 5-65; Col. 29 lines 40-65).

18. US '637 teaches that the immunogen may be conjugated via chemical crosslinking or expressed a fusion protein to glycols such as propylene glycol or polyethylene glycol thus meeting the limitations of claims 4, 7, 15, 16, 17, 18, 19, 25, 64, and 65 (Col. 20-24; Col. 27 lines 35-56; Col. 29-30).

19. US '637 teaches that the immunogen is capable of inducing an immunological response against itself thus meeting the limitations of claims 9 and 26 (Col. 20-24; Col. 27 lines 35-56; Col. 29-30).

20. US '637 teaches that the administration of the immunogen may be at least one a year, twice a year, or three times a year, in the range of 1-500 μg per patient via one or any of the following routes parenteral, peritoneal (intraperiotoneal), oral, intracranial, intramuscular (which encompasses buccal), suppositories (which encompasses anal), and intravenous (which encompasses spinal and epidural) by means of a sustained release device (encompassing a VLN) thus meeting the limitations of claims 27, 28, 29, 33, 66, 67, and 68 (Col. 26 lines 36-65; Col. 27 lines 35-56; Col. 30 lines 15-45).

21. Claims **1, 10, 27, 28, 33, 59, 60, 65, 70, 71, 73, 74,** and **76** are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent Application Publication US 2002/0077288 A1 (20 June 2002) Frangione *et al.*

22. US '288 teaches a method of treating a disease associated with amyloid deposits of Aβ in the brain of a patient including but not limited to Alzheimer's disease comprising administering an immunogenic Aβ fragment conjugated to a T helper cell and/or B-cell epitope as part of a polyhydroxypolymer carrier backbone such as mannan and glucan thus meeting the limitations of claims 1, 65, 70, 71, 73, 74, and 76 (**[0006], [0027]-[0030], [0060]-[0063], [0125]**).

23. The teachings of US '288 include human amino acid sequences as well as variants such as but not limited to Aβ and APP including APP770. Also the sequence listings of

US '288 fully encompass the residues 672-714 and 700-714 of the amino acid sequence of instant SEQ ID NO: 2 (see Sequence Listing).

24. The teachings of US '288 include but are not limited to helper T cells such as tetanus toxoid, pertussis toxin (also known as diptheria), *P. falciparum* CS epitope, B-cell epitopes, promiscuous T_H epitopes, and MHC II epitopes thus meeting the limitations of claims 10, 59, and 60 (**[0060]-[0063]**).

25. US '288 teaches that the administration of the immunogenic conjugate may be at least one a year, in the range of 0.5 μg to 1 mg per patient through the parenteral or oral routes thus meeting the limitations of claims 27, 28, and 33 (**[0075]-[0077]**).

26. Claims **1, 10, 59, 60, 69, 70, 71, 73, 74,** and **76** are rejected under 35 U.S.C. 102(e) as being anticipated by US 6,787,523 B1 (7 September 2004) Schenk.

27. US '523 teaches a method of treating a disease associated with amyloid deposits of Aβ in the brain of a patient including but not limited to Alzheimer's disease comprising administering an immunogenic Aβ fragment conjugated to a T helper cell and/or B-cell epitope as part of a polyglocolide copolymer (PLPG) thus meeting the limitations of claims 1, 70, 71, 73, 74, and 76 (Col. 2-3; Col. 6-11).

28. The teachings of US '523 include all natural human amino acid sequences as well as analogs such as but not limited to allelic, species, and induced variants of Aβ and APP including APP770. Also the sequence listings of US '523 fully encompass the residues 672-714 and 700-714 of the amino acid sequence of instant SEQ ID NO: 2 (see Sequence Listing; Col. 6 lines 40-67).

29. The teachings of US '523 include but are not limited to helper T cells such as tetanus toxoid, diptheria, influenza Hemagluttinin HA, malaria CS (*P. falciparum* is the causative agent of malaria thus the two epitopes are the same), and MHC II epitopes thus meeting the limitations of claims 10, 59, 60, and 69 (Col. 20 lines 20-60).

30. US '523 teaches that the administration of the immunogen may be at least one a year, twice a year, or three times a year, in the range of 1-500 μg per patient via one or any of the following routes parenteral, peritoneal (intraperiotoneal), oral, intracranial, intramuscular (which encompasses buccal), suppositories (which encompasses anal), and intravenous (which encompasses spinal and epidural) by means of a sustained release device (encompassing a VLN) thus meeting the limitations of claims 27, 28, 29, 33, 66, 67, and 68 (Col. 2-3; Col. 14-17).

Summary

31. Claims **1, 3, 4, 7-10, 15-19, 25-29, 33, 59, 60,** and **62-76** are hereby rejected.

32. The following articles, patents, and published patent applications were found by the Examiner during the art search while not relied upon for the instant rejection(s) are considered pertinent to the instant application:

a. US 6713450 B2 (30 March 2004) Frangione *et al.*

b. US 2004/0091945 A1 (13 May 2004) Fitzer-Attas *et al.*

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Christopher James Nichols, Ph.D.** whose telephone number is **(571) 272-0889**. The examiner can normally be reached on Monday through Friday, 8:00 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Brenda Brumback** can be reached on **(571) 272-0961**.

The fax number for the organization where this application or proceeding is assigned is **703-872-9306**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see **http://pair-direct.uspto.gov**. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

Elizabeth C. Kemmerer

CJN
October 6, 2004

ELIZABETH KEMMERER
PRIMARY EXAMINER